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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,562	04/19/2001	Edward Larry McCleary	12439.101B	7515

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EXAMINER
MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
1623	12

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/837,562	MCCLEARY, EDWARD LARRY	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *3,5,7-9,11,14-23,25,26,28,30-32,34 and 37-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,10,12,13,24,27,29,33,35,36 and 46-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure statement filed August 7, 2001 and only the references which were provided in English have been taken into consideration.

Election/Restrictions

Applicant's species election in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Additionally, it is pointed out that applicant has elected the claims which read on the species chosen, being claims 1, 2, 4, 6, 10-14, 24, 25, 27, 29, 33-37 and 46-52. The Examiner notes that elected claims 11, 14, 34 and 37 are all drawn to a plurality of species, including non-elected species, and therefore have not been treated on the merits in the instant office action. It is further noted, that elected claims 10, 11, 33, 34, and 46-49 are all dependent upon nonelected claims. These claims will be treated in a manner in which they read on the elected claims from which they ultimately depend from which read on the species elected.

An action on the merits of claims 1, 2, 4, 6, 10, 12, 13, 24, 27, 29, 33, 35, 36, and 46-52 is contained herein below.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 15, lines 17-18. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 10, 12, 13, 24, 27, 29, 33, 35, 36, and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

Claims 1 and 24 describe a composition which contains 6 different active agents (A-F). Claims 6 and 29 limit one of the active agents to a "methyl donor". These active agents are disclosed by their function, not by their names (e.g. "at least one agent which promotes synthesis of ATP and/or creatine phosphate in the body"). Describing an active agent which is to be used in the composition by it's function, i.e. for down-regulating cortisol action, or a methyl donor, will not substitute for the written description of the structure or chemical name of the compound. The invention should be described in such a way as to describe what the invention is, not what the invention does. Describing the agents intended to be incorporated into the composition as

claimed by their function fails to distinguish the compound intended from other molecules that can perform the same function.

Claims 24, 27, 29, 33, 35, 36, and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant disclosure is not seen to be sufficient to enable the use of any compound which comprises active agents A-F, to normalize impaired or deteriorating neurological function without undue experimentation.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in ***In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)***. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims – The nature of the invention

Claim 24 is drawn to a method for normalizing impaired or deteriorating neurological function in a human comprising administering a composition comprising:

(A) an agent which promotes ATP and or creatine phosphate synthesis;

(B) an antioxidant for scavenging free radicals in at least one pathway in the body;

(C) an agent for normalizing or maintaining membrane function and structure;

(D) an agent for normalizing or maintaining normal neurotransmitter function;

(E) an agent for down-regulating cortisol action; and

(F) an agent for suppressing activation of apoptotic pathways.

Dependent claims 25, 27, 29, 33, 35, and 36 limit the active agents wherein (A) is B-vitamins, (B) is ALA, (C) is a methyl-donor, (D) is huperzine A, (E) is pyridoxine, and (F) is vinpocetine respectively. Claim 46 further defines the composition by incorporating other agents. Claims 47-49 provide dosage amounts and intake regiments for the composition. Claims 50-52 add additional method steps, wherein patient follows further stress reduction, cognitive retraining, or dietary plans/programs. It is noted that the claims read on treating and curing any and all diseases relating to the nervous system and neurological disorders, including curing paralysis, multiple sclerosis, and Alzheimer's Disease.

The state of the prior art

Neurological disorders and nervous system diseases are known to be localized in the following sites: muscle, motor end plate, peripheral nerves, spinal nerve roots, spinal cord, brainstem, cerebellum, basal ganglia and thalamus, and cerebral hemispheres. Pathologies include genetic disease, infections, trauma, neoplasms, metabolic disorders, toxic disorders,

endocrine disorders, vascular diseases, demyelinating and degenerative disease, electrical disorders, and autoimmune disorders. Nervous system and neurological diseases can belong to the following classes: the peripheral system diseases, disease of the neuromuscular junction, diseases of muscle, the spinal cord, cranial nerves, the cerebellum, the basal ganglia, the cerebrum, unlocalized or multifocal disorders, and demyelinating diseases. Heavy metals (e.g., arsenic, lead, thallium, gold, manganese, and mercury), synthetic chemicals (e.g., organophosphates, gasoline, and toluene), alcohols (especially ethyl and methyl alcohol), ionizing radiation, and many drugs can all be toxic to the nervous system. In addition, water overload can cause seizures, and oxygen, under high pressure, can induce depression of brain function. Many drugs and other agents are capable of causing damage to cranial nerves or peripheral nerves. There are compounds which are known to have beneficial effects on certain nervous system disorders, for example, human phosphoprotein polypeptide (hPSHP) - useful for treating degenerative neuronal diseases e.g. Parkinson's and Huntington's disease (Hillman et al. 5,971,028), but none are known to cure all nervous system disorders.

Pyridoxine (vitamin B_6) is a well-known vitamin normally used as an adjunct in prophylaxis and treatment of multiple vitamin B complex deficiencies. It is also used in dermatoses, neuromuscular and neurological diseases as seen in Coffen et al. (Us Patent 4,026,901).

Lipoic acid prevents free radical damage to cells and cell components and has been shown to maintain microsomal protein thiols, protect against hemolysis, and protect against neurological disorders as seen in Perricone et al. (US Patent 5,709,868).

Compositions comprising methyl donors, particularly methylcobalamin, provide a method for treating a host with neurological dysfunction associated with an immunological disorder. The methyl donor compounds are also used to restore normal metabolic biochemical functions after immune mediated disruption of biochemical pathways as seen in Rabinoff et al. (US patent 5,508,271).

Acetylcholinesterase inhibitors (e.g., huperzine A and B) provide relief of symptoms of apathy, delusions, hallucinations and irritability in Alzheimer's disease patients as seen in Kaminski et al. (US Patent 5,889,033).

Vinpocetine possesses antioxidant activity which exerts significant protective action in events of cerebral ischemia (transient ischemic attack (TIA), stroke), where the injury of learning and memory may occur in addition to neurological symptoms of various severity as seen in Szantay et al. (US Patent 6,093,720).

As with all compositions containing multiple active agents, one would appreciate that the parameters surrounding each compound used in a combination for use in treatment will vary depending on a multitude of conditions, including the disease treated, the particular compounds used, the route of administration, and the condition and age of the patient. Additionally, one would recognize the possibilities of compounds having either synergistic or deleterious effects upon each other due to the reactions they can undergo with each other.

The level of one of ordinary skill

The skilled artisan in this field is that of an MD for neurological disorders and/or a PhD skilled in the development of therapeutics for neurological disorders.

The level of predictability in the art

The examiner acknowledges the probability and predictability that the active agents independently selected, indeed have efficacy in treating certain specific symptoms associated with certain specific neurological disorders, however the art appears to be silent with regard to the predictability of effectively treating and curing all neurological disorders by administering any of the indicated compounds, or in their combination. One skilled in the art would not predict from the disclosure that all neurological disorders or symptoms could be effectively treated and cured by administering the composition of the instant application.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate within the scope of the claims. There are no control groups where a skilled artisan could conclusively state that the positive effects are tied to the administration of the combined compounds. There is no data which adequately represent the complete scope of the claims as written. Further, there is no evidence in the disclosure that the composition as claimed would have any beneficial effect on a human patient. Although the instant specification provides guidance on various pathways involved in neurological activity, it is not seen to provide guidance for the use of the composition as claimed to effectively act in the manner claimed.

The existence of working examples

There are no working examples set forth in the instant specification.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the use of the composition as claimed, to treat and/or cure any/all neurological disorders or symptoms without undue experimentation. One skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 6, 10, 12, 13, 24, 27, 29, 33, 35, 36, and 46-52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claim 24 are drawn to "methods for normalizing impaired or deteriorating neurological function in a human...". It is unclear exactly that which applicant intends by this recitation. Is it a method for normalizing impaired neurological function or deteriorating neurological function in a human? Or is it a method for normalizing impaired neurological function or normalizing deteriorating neurological function in a human? Clarity is respectfully requested. It is noted the examiner is interpreting the claims as a method for normalizing impaired neurological function or normalizing deteriorating neurological function in a human.

The terms "normalizing" and "normal" in claims 1 and 24 are relative terms which render the claims indefinite. The terms "normalizing" and "normal" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What

level is meant to be normal, and what level is not intended as normal? Clarity is respectfully requested.

The term "impaired" in claims 1 and 24 is a relative term which renders the claim indefinite. The term "impaired" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What level of impairment is intended to be encompassed? Clarity is respectfully requested.

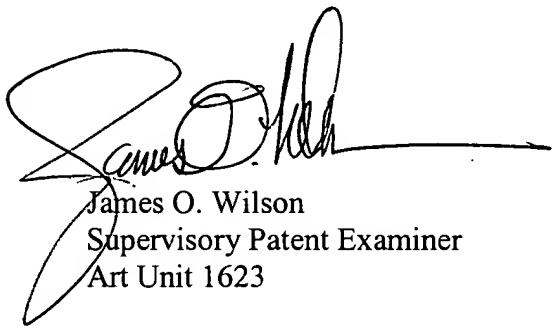
The term "deteriorating" in claims 1 and 24 is a relative term which renders the claim indefinite. The term "deteriorating" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What level of deterioration is intended to be encompassed? Clarity is respectfully requested.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh
January 30, 2003